

CERTIFICATE OF COMPLIANCE

STERIKING® SS-T – Self-Sealable See-Through packages are converted from transparent plastic film and paper. They are developed for packing medical items for steam and ethylene oxide sterilization procedures. The packages contain two class 1 process indicators (EN ISO 11140-1:2005): one for steam and one for ethylene oxide printed on pouch and indicators are printed also on tape liner.

The process indicators are developed to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units.

TECHNICAL DATA

The colour change occurs after exposure to the following conditions:

Performance requirements			
<i>Indicator type</i>	<i>Process conditions</i>	<i>Start -> End colour</i>	<i>Test result</i>
STEAM	Saturated steam for 3 min ± 5 s at 121°C (+3/0 °C)		Incomplete colour change
STEAM	Saturated steam for 30 s (± 5 s) at 134°C (+3/0 °C)		Incomplete colour change
STEAM	Saturated steam for 10 min ± 5 s at 121°C (+3/0 °C)	Pink to Brown	Complete colour change
STEAM	Saturated steam for 2 min ± 5 s at 134°C (+3/0 °C)	Pink to Brown	Complete colour change

Performance requirements			
<i>Indicator type</i>	<i>Process conditions</i>	<i>Start -> End colour</i>	<i>Test result</i>
EO	90 min ± 1 min at 60°C ± 2 °C , ≥ 85% RH, no EO concentration		No colour change
EO	5 min ± 15 s at 30°C ± 1 °C , 60% ± 10 % RH, EO 600 mg/l ± 30 mg/l		Incomplete colour change
EO	2 min ± 15 s at 54°C ± 1 °C , 60% ± 10 % RH, EO 600 mg/l ± 30 mg/l		Incomplete colour change
EO	30 min ± 15 s at 30°C ± 1 °C, 60% ± 10 % RH, EO 600 mg/l ± 30 mg/l	Transparent to Gold/Ocra	Complete colour change
EO	20 min ± 15 s, at 54°C ± 1 °C, 60% ± 10 % RH, EO 600 mg/l ± 30 mg/l	Transparent to Gold/Ocra	Complete colour change

HEALTH AND SAFETY

In proper and correct used of sterilization packaging, the process indicators have not been found to cause any harm or safety risk before, during or after the sterilization process.

SHELF LIFE

The shelf life of the final product is two years from the date of manufacture when stored in their sales packaging. The colour change is clearly visible to naked eye and it is permanent. When once changed, the indicator does not fade or turn back its start colour, when properly stored.